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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,444

02/17/2004

Peter M. Bonutti

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EXAMINER

SZPIRA, JULIE ANN

ART UNIT

PAPER NUMBER

4148

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DELIVERY MODE

03/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/780,444	<b>Applicant(s)</b> BONUTTI ET AL.	
	<b>Examiner</b> JULIE A. SZPIRA	<b>Art Unit</b> 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2/17/2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 and 25-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-8 and 18-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/2004</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of claims 1-8 and 18-24 in the reply filed on October 7<sup>th</sup>, 2007 is acknowledged.
2. Claims 9-17 and 25-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and method, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 7<sup>th</sup>, 2007.

### *Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 19 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Merritt (US 5,208,950).

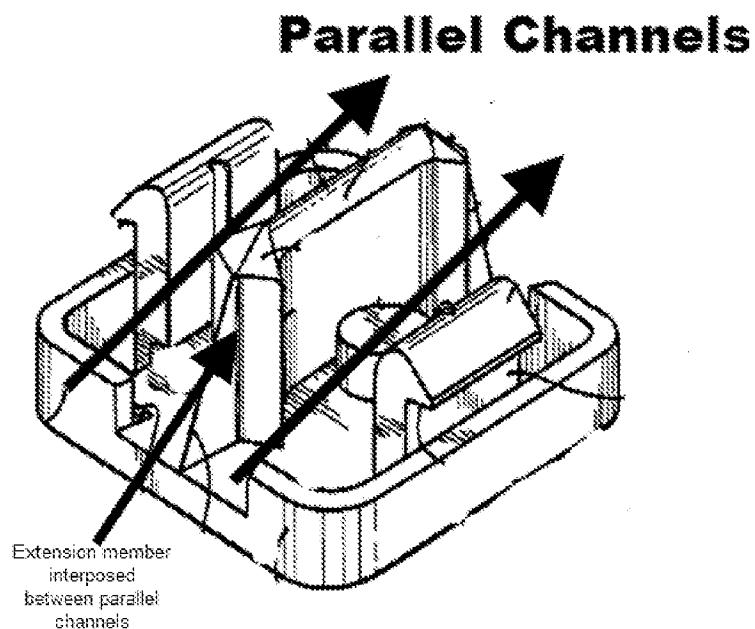
**Regarding claim 1**, Merritt discloses a device that is capable of acting as a suture holder (cord lock, 10) capable of securing a suture relative to a body tissue comprising a first (male body, 14) section including an extension member (projection, 66) and a second (female body, 12) section configured for receiving the extension member (recess, 35), the first and second section being bondable together with the application of an energy source (ultrasonic welding; column 4, lines 35-36).

The device described by Merritt has the claimed structural limitations recited by the applicant. The recitation of intended use is not given patentable weight in this case, as the prior art apparatus satisfies the claimed subject matter.

**Regarding claim 2**, Merritt discloses the suture (cord) interposed between the first and second sections (column 3, lines 15-18)

**Regarding claim 3**, Merritt discloses the first and second section bonded (snap-locked) together to secure the suture (column 4, lines 13-20)

**Regarding claim 4**, Merritt discloses the first section including a pair of parallel channels (Figure 4, see below)



**Regarding claim 5**, Merritt discloses the extension member (66) interposed between the pair of parallel channels (Figure 4, see above)

**Regarding claim 6**, Merritt discloses the second section including a channel (recess, 35) configured for receiving the extension member (column 3, lines 56-59)

**Regarding claim 7**, Merritt discloses the suture (cord) including a first (19) and second (21) end, one each position able within the parallel channels (column 3, lines 62-64; Figure 1).

**Regarding claim 8**, Merritt discloses the suture interposed between the first and second sections when the extension member is positioned within the channel (column 4, lines 16-20).

**Regarding claim 19**, Merritt discloses the first and second sections interconnected by a system of pins and recesses (column 4, lines 11-16).

**Regarding claim 24**, Merritt discloses the energy source being ultrasonic energy (welding) (column 4, lines 33-36)

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. **Claim 18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Merritt.

**Regarding claim 18**, Merritt discloses the first section of the retainer being textured (having projections; column 3, lines 65-68) to aid in gripping the suture (cord). Merritt fails to disclose the second section also being textured.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to texture the first and second sections since it has been held that the duplication of essential working parts (textured surfaces) of a device involves only routine skill in the art.

6. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt** in view of **Hart (US 5,630,824)**.

**Regarding claim 20**, Merritt discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of a biodegradable material.

However, Hart teaches a suture retainer (attachment device) made of a biodegradable polymer (column 4, lines 50-52).

Despite the invention of Merritt being disclosed as a cord holder, its structural limitations would allow the device to behave as a suture holder, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder out of a biodegradable material so the device can dissolve after the wound which the suture is attached to heals (column 4, lines 52-65).

7. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt** in view of **Tokushige et al. (US 5,866,634)**

**Regarding claim 21**, Merritt discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of heat shrink material.

However, Tokushige et al. teaches a biodegradable shrink material that has superior strength, flexibility, and the ability to shrink at lower temperatures (column 1, lines 39-42; column 4, lines 19-22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder out of a heat shrink material because it would allow the suture retainer to shrink around the suture (container) with minimal warping (wrinkling) (column 3, lines 24-26)

8. **Claims 22 and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt** in view of **Bartlett (US 5,879,372)**,

**Regarding claims 22 and 23**, Merritt discloses the invention substantially as claimed above, but fails to disclose the suture retainer including viable cells or pharmaceutical agents.

However, Bartlett teaches the suture retainer (anchor) including viable cells (bone tissue) and pharmaceutical agent (hydroxyapatite) (column 4, lines 34-36 and 46-50).

Despite the invention of Merritt being disclosed as a cord holder, its structural limitations would allow the device to behave as a suture holder, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to include viable cells and a pharmaceutical agent to strengthen the area in which the device is placed (column 4, lines 24-26).

***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Egan** (US 6,174,324 B1), **Murai** (US 5,671,508), and **Weppner et al.** (US 5,504,977),

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571)270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/  
Examiner, Art Unit 4148



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/Terrell L Mckinnon/

Supervisory Patent Examiner, Art Unit 4148